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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------|
| 10/606,471 | 06/25/2003 | Abram Katz | 13425-115001 / BV-1025 | 3516 |
| 26161 | 7590 | 05/26/2006 | US | |
| FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | EXAMINER WOOD, AMANDA P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1655 | |
| DATE MAILED: 05/26/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/606,471 | Applicant(s) KATZ ET AL. | |
| | Examiner Amanda P. Wood | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7 and 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION-Final Rejection

Applicant's arguments and amendments filed 5 April 2006 are acknowledged and have been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Claim Rejections - 35 USC § 103

Claims 1, 4, 7, and 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birnbaumer et al (US 5,932,417) in view of Draznin et al, for the reasons set forth in the previous office action, and further in view of Bruton et al (Acta Physiol Scan 2001).

Methods for identifying an agent that increases glucose uptake in a mammalian cell are claimed.

Birnbaumer et al teach methods for controlling capacitative calcium entry (i.e., CCE, store-mediated calcium entry, or SMCE) in a mammalian cell, wherein compounds and other agents are screened to determine if they are useful in controlling CCE. For example, the screening method involves exposing the cell to a potential drug or other compound and determining if the level of trp protein (i.e., a store-mediated calcium entry-regulating factor) is reduced, thereby reducing (i.e., modulating) calcium ion entry into the cell. Furthermore, Birnbaumer et al specifically teach that not only agents that block calcium entry due to trp expression but also agents that stimulate

calcium entry can be screened in this way. In particular, Birnbaumer et al teach that stimulation of pancreatic β -cell CCE stimulates insulin secretion in type II diabetic patients, thereby increasing insulin-stimulated glucose uptake (see, for example, col. 15, lines 5-60, and col. 16, lines 1-40).

Draznin et al beneficially teaches that intracellular calcium concentrations may exert a dual role in the regulation of cellular sensitivity to insulin, wherein a minimal concentration of intracellular calcium must exist to promote insulin action and also an increased level of intracellular calcium may provide a critical signal for decreased insulin action. Draznin et al further teach that it is possible that intact calcium ion fluxes in and out of cells may be required to maintain an optimal rate of glucose transport. In addition, Draznin et al teach that increased concentrations of intracellular calcium deactivated calcium channels and reduced the rate of calcium flux. Therefore, Draznin et al beneficially teach that if maintenance of calcium flux is required to optimize glucose transport, then deactivation of this process by high and/or sustained intracellular concentrations of calcium may result in a decrease of insulin-stimulated glucose uptake (see, for example, Abstract, and pg. 14388, col. 1, pgh. 3, and col. 2).

Bruton et al beneficially teach that based upon a collection of information from various sources, calcium is necessary for insulin-stimulated glucose uptake. In particular, Bruton et al teach that Cartree et al found that calcium channel blockers such as nifedipine reduce insulin-stimulated glucose uptake in rat skeletal muscle. Furthermore, Bruton et al report that Draznin et al, as discussed above, examined the possibility that calcium could have biphasic effects on insulin-stimulated glucose uptake,

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finding that in adipocytes large increases in calcium inhibited insulin-stimulated glucose uptake, whereas small rises in calcium were stimulatory (see, for example, pg. 262, col. 1-2).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Birnbaumer et al based upon the beneficial teachings provided by the secondary references with respect to the art-recognized importance of intracellular calcium levels to insulin-stimulated glucose uptake. Furthermore, the Draznin et al and Bruton et al particularly point out that calcium channel blockers reduce insulin-stimulated glucose uptake and that small rises in intracellular calcium stimulate insulin-stimulated glucose uptake, and therefore, it would have been both obvious and beneficial for the skilled artisan to modify the methods taught by Birnbaumer et al so as to test candidate agents to determine whether they increase capacitative calcium entry, and thereby increase insulin-stimulated glucose uptake in mammalian skeletal muscle cells.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to claims 1, 4, and 7 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. P. Wood
Examiner
Art Unit 1655

APW



CHRISTOPHER R. TATE
PRIMARY EXAMINER